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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1611	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/574,934	MIYATA ET AL.	
	Examiner	Art Unit	
	Isis A. Ghali	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 September 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *17,20 and 26-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17,20 and 26-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' amendment filed 09/02/2009.

Claims 1-16, 18, 19, 21-25 have been canceled, and claims 31-32 have been added.

Claims 17, 20, 26-20 are pending and included in the prosecution.

The following rejections have been overcome by virtue of applicants' amendment and remarks:

The rejection of claim 24 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The rejection of claims 21, 22, 24 under 35 U.S.C. 112, second paragraph, as being indefinite.

The following new ground of rejections are necessitated by applicants' amendment:

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

> art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 17, 20, 26-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amended claims recite "said composition being **free of gluconic acid**". Nowhere applicant disclosed composition free of gluconic acid. Applicants state that examples 1-9 do not are free of gluconic acid. However, applicant disclosed fatty acids in general in paragraph 16 of the published application:

> "The term "fatty acids" as referred to as in the present invention means fatty acids and derivatives thereof in general, which exert the action of enhancing collagen production when used in combination with L-ascorbic acids. Concrete examples of such are straight or branched saturated or unsaturated fatty acids with carbon atom numbers of at least three, and derivatives thereof; preferably, straight or branched saturated or unsaturated fatty acids with carbon atom numbers of at least ten, and derivatives thereof; more preferably, straight or branched saturated or unsaturated fatty acids with carbon atom numbers of between 10 and 18, and derivatives thereof. Among the above fatty acids, 10-HDA, 10- hydroxydecanoic acid, decanoic acid, 2-decenoic acid, sebacic acid, and derivatives thereof are most preferably used. These fatty acids also enhance the production of transforming growth factor (hereinafter called "TGF-B") in fibroblasts in the presence of L-ascorbic acids. Since TGF-B is known to be produced by keratinocytes existing in intraepidermal tissues of the skin, it is suggested that fatty acids correlate to the mechanism of TGF-B production by keratinocytes."

Therefore, no disclosure of composition free of gluconic acid. Applicants disclosed fatty acids straight or branched saturated or unsaturated fatty acids with carbon atom numbers of at least three, and derivatives thereof. Applicants' exemplification of representative of fatty acids does not exclude other fatty acids encompassed by the disclosure and claims.

It has been held that "Any negative limitation or exclusionary proviso must have basis in the original disclosure." See In re Johnson, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977). In *In re Johnson*, the court noted that any negative limitation or exclusionary proviso *must have basis in the original disclosure*. *Only* if alternative elements are positively recited in the specification, they may be explicitly excluded in the claims. In the present case the negative limitation/exclusionary proviso does not have basis in the original disclosure, and the alternative elements were not positively recited in the specification, they are generically disclosed. See also *Ex parte Grasselli*, 231 USPQ 393 (Bd. App. 1983), aff'd mem., 738 F.2d 453 (Fed. Cir. 1984). Any claim containing a negative limitation, which does not have basis in the original disclosure, should be rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement. In *Purdue Pharma LP v Faulding, Inc., 230 F.3d 1320, 1326, 56 USPQ2d 1481, 1486 (Fed. Cir. 2000)*, the court noted that with respect to *In re Ruschig, 371 F.2d 990, 154 USPQ 118 (CCPA 1967)*, "Ruschig makes clear that one cannot disclose a forest in the original application, and then later pick out a tree of the forest and say, "here is my invention". In order to satisfy the written description requirement, the blaze marks directing the skilled artisan to that tree must be in the originally filed disclosure." *Purdue* is relevant in this case, because the Applicants disclosed a genus ("a forest") in the original application, then later picked out two specific compounds ("a tree of the forest"), and are now saying, "here is my invention". In order to satisfy the written description requirement, according to *Purdue*, the Applicants must disclose the specific compounds in the originally filed disclosure." (See

(56 USPQ2D 1481). More from *Purdue*: The case of *In re Ruschig*, 379 F.2d 990, 154 USPQ 118 (CCPA 1967), is instructive here (see page 1487). The claim at issue in that case was directed to a single compound. The appellants argued that, although the compound itself was not disclosed, one skilled in the art would find support for the claimed compound in the general disclosure of the genus of compounds to which the claimed compound belonged. The Ruschig court rejected that argument, stating: [i]t is an old custom in the woods to mark trails by making blaze marks on the trees. It is of no help in finding a trail or in finding one's way through the woods where the trails have disappeared-or have not yet been made, which is more like the case here-to be confronted simply by a large number of unmarked trees. We are looking for blaze marks, which single out particular trees. We see none. *Id.* at 994-95, 154 USPQ at 122.

In accordance to MPEP 714.02, applicant should specifically point out to where in the disclosure a support for any amendment made to the claims can be found.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 17, 20, 26-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 17 recites the limitation "L-ascorbic acid" in the 9th and 11th lines of the claim. There is insufficient antecedent basis for this limitation in the claim.

6. Claim 31 recites the limitation "L-ascorbic acid" in the 7th and 9th lines of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

8. Claims 17, 20, 27-31 are rejected under 35 U.S.C. 102(a) as being anticipated by JP 2003-171290 (‘290) as evident by JP 10-147514 (‘514) or JP 09-315928 (‘928).

JP ‘290 discloses method for producing collagen production potentiator capable of continuously exhibiting action of potentiating the collagen production by using composition comprising L-ascorbic acid and royal jelly as active ingredient (abstract; paragraph 0008). The L-ascorbic acid is L-ascorbic acid 2-glycoside including L-ascorbic acid 2-glucoside (paragraph 0011). The composition comprising by weight 0.001 to 20% of L-ascorbic acid derivative or royal jelly (paragraph 0019), this disclosure of the reference implied that the royal jelly can be present in the same amount as the L-ascorbic acid derivative, and this meets the limitation of claim 22 that the royal jelly is present in an amount up to one part of the ascorbic acid. JP '290 disclosed that the composition can be a cosmetic, food, quasi drug or feed (claim 10, paragraph 0019). The composition further comprises antioxidant, thickeners, sugar and

sugar alcohol, gums, water, alcohol, amino acid, vitamin, mineral flavor, emulsifier, seasoning, spices (paragraphs: 0015-0020). Royal jelly inherently contains 10-hydroxy-2-decenoic acid as evident by the disclosure of JP '514 as it discloses that 10-hydroxy-2-decenoic acid is an active ingredient of royal jelly (Problem to be solved; paragraphs 0005, 0012). Inherency of royal jelly content of the claimed fatty acids is further evident by JP '928 that discloses compounds of royal jelly origin comprising 10-hydroxy-2-decenoic acid, decanoic acid, 2-decenoic acid, sebacic acid (abstract; paragraphs 0007; claims 1 and 2).

The limitations of claims 17, 20, 27-31 are met by JP '290.

Response to Arguments

9. Applicant's arguments filed 09/02/2009 have been fully considered but they are not persuasive.

Applicants argue that claim 17 as amended recites the composition is free of gluconic acid. Miyata composition contains gluconic acid because the composition contains royal jelly and gluconic acid is one of the ingredients of royal jelly. Claim 17 recites a method using a composition that does not contain royal jelly, but only the active ingredients thereof.

In response to this argument, applicants' attention is directed to the "comprising" language of the present claims that does not exclude the presence of gluconic acid. In re *Mannesmann Demag Corp. v. Engineered Metal Products Co.*, 793 F.2d 1279, 230 USPQ 45 (Fed. Cir. 1986), and *In re Crish*, 393 F.3d 1253, 73 USPQ2d 1364 (Fed. Cir.

2004), the court stated that the use of "consists" in the body of the claims did not limit the open-ended "comprising" language in the claims (emphases added). Id. At 1257, 73 USPQ2d at 1367. The court affirmed the Board's interpretation that the transition phrase "consists" did not limit the claims to only the recited members, and that "the transition language comprising" allowed the claims to cover other members. This applies in the present case because claims 17 and 31 are open-ended. Further, it has been held that omission of an element and its function is obvious if the function of the element is not desired. *Ex parte Wu*, 10 USPQ 2031 (Bd. Pat. App. & Inter. 1989). See also *In re Larson*, 340 F.2d 965, 144 USPQ 347 (CCPA 1965); and *In re Kuhle*, 526 F.2d 553, 188 USPQ 7 (CCPA 1975). In this case applicants decided to eliminate gluconic acid. It is further argued that Miyata reference teaches royal jelly and the active ingredient of royal jelly is 10-hydroxy-2-decenoic acid as evident by JP '514 and JP '928. JP '514 and JP '928 do not teach gluconic acid in the royal jelly. Additionally, the present claims are not directed to isolated fatty acid. As a matter of fact the present example 7 uses royal jelly as a whole as source of fatty acid.

Applicants argue that royal jelly is a natural substance and therefore contains various substances, such as those that cause unpleasant odors, those that tend to induce allergic reactions, those which color a composition, etc. There are no extraneous substances present in the composition of the present invention that might cause malodors, discoloration of the composition, or allergens.

In response to this argument, it is argued that the present claims are not directed to fatty acids isolated from royal jelly, and as stated previously present example 7 uses royal jelly as a whole as source of fatty acid. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., no extraneous substances present in the composition of the present invention that might cause malodors, discoloration of the composition, or allergens) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicants argue that the present inventors have succeeded in identifying what compounds in royal jelly are effective in enhancing the collagen production of a saccharide derivative of L-ascorbic acid.

In response to this argument, it is argued that the prior art recognized and disclosed the effect of the compound of royal jelly in combination with saccharide derivative of L-ascorbic acid to enhance collagen formation. This is exactly what applicants have done. In response to the argument that inventors have succeeded in identifying what compounds in royal jelly are effective in enhancing the collagen production of a saccharide derivative of L-ascorbic acid, it is argued that this is not impressive absent a showing that the art tried and failed to solve the same problem notwithstanding its presumed knowledge of the references. See *In re Wright*, 569

F.2d 1124, 193 USPQ 332 (CCPA 1977). The fatty acids of royal jelly and their effect on collagen were known at the time of the invention. The discovery of a new action underlying a known process or composition does not make it patentable. *MEHL/Biophile*, 192 F.3d at 1365, 52 U.S.P.Q.2d at 1303. Also, it is irrelevant that the prior art observers did not recognize the property or function of the disputed claim; if the prior art inherently possessed that characteristic, it anticipates. See *Verdeegal Brothers, Inc. v. Union Oil Co. of Cal.,* 814 F.2d 628, 633, 2 U.S.P.Q.2d 1051, 1054 (Fed. Cir. 1987). Further, it has been held that omission of an element and its function is obvious if the function of the element is not desired. *Ex parte Wu*, 10 USPQ 2031 (Bd. Pat. App. & Inter. 1989). See also *In re Larson*, 340 F.2d 965, 144 USPQ 347 (CCPA 1965); and *In re Kuhle*, 526 F.2d 553, 188 USPQ 7 (CCPA 1975). In this case applicants decided to eliminate gluconic acid.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 26 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 2003-171290 (‘290) as evident by JP 10-147514 (‘514) or JP 09-315928 (‘928) by them selves or further in view of JP 2000-159656 (‘656), its translated abstract provided by applicant in the IDS filed 04/28/2009, and full translated document is provided by the examiner attached to this office action.

The teachings of JP ‘290 are previously discussed as set forth in this office action.

JP '290 further teach cosmetics that containing mucopolysaccharides such as hyaluronic acid have been developed as cosmetic for aging prevention in order to secure the moistness of the skin (paragraph 0006).

Therefore, as admitted by JP '290, at the time of the invention it was known to include hyaluronic acid in cosmetic composition. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to include hyaluronic acid in the composition comprising saccharide derivative of L-ascorbic acid and royal jelly. One would have been motivated to do so because JP '290 teaches that hyaluronic acid is known to be included in cosmetic for aging prevention in order to secure the moistness of the skin. One would reasonably expected formulating composition comprising saccharide derivative of L-ascorbic acid, royal jelly and hyaluronic acid, wherein the composition potentiates the production of collagen and prevents aging and further secures the moistness of the skin.

Further, JP '656 teaches cosmetic composition having collagen synthesis accelerating effect, excellent in stability and provides cosmetic excellent in wrinkles prevention (abstract). The composition comprises ascorbic acid derivative and hyaluronic acid (paragraphs 0010, 0017, 0018).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide composition comprising saccharide derivative of L-ascorbic acid and royal jelly to accelerate collagen formation as taught by JP '290, and further add hyaluronic acid taught by JP '656 o the composition. One would have been motivated to do so because JP '656 teaches that composition comprising hyaluronic acid and ascorbic acid derivatives provides collagen synthesis accelerating effect, excellent in stability and provides cosmetic excellent in wrinkles prevention. One would reasonably expected formulating composition comprising saccharide derivative of L-

ascorbic acid, royal jelly and hyaluronic acid, wherein the composition have collagen synthesis accelerating effect and excellent in wrinkles prevention, meanwhile is table composition.

Response to Arguments

14. Applicant's arguments filed 09/02/2009 have been fully considered but they are not persuasive.

Applicants repeats the argument regarding Miyata reference as evident by JP '514 and JP '928, and further argue that Nanbu adds nothing to Miyata, because Nanbu merely discloses the combination of L-ascorbic acid and hyaluronic acid.

In response to this argument it is argued that Nanbu is relied upon for the solely teaching of cosmetic composition comprises combination of ascorbic acid derivative and hyaluronic acid. Further, Nanbu teaches the composition to have collagen synthesis accelerating effect, excellent in stability and provides cosmetic excellent in wrinkles prevention. Miyata also recognized inclusion of hyaluronic acid in cosmetic composition. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to include hyaluronic acid in the composition comprising saccharide derivative of L-ascorbic acid and fatty acids of royal jelly. Therefore the combination of combination of hyaluronic acid with ascorbic acid derivatives in cosmetics was obvious at the time of the invention.

15. Claims 17, 20, 26-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of JP 2000-159656 ('656), its translated abstract provided by applicant in the IDS filed 04/28/2009, and full translated document is provided by the examiner attached to this office action, combined with JP 09-030921 ('921) and further combined with JP 09-315928 ('928), translation of both is provided by the examiner attached to this office action.

Applicant's claims

Claim 17 as currently presented is directed to method for enhancing collagen production comprising administering a composition comprising (i) a saccharide derivative of L-ascorbic acid and (ii) a fatty acid selected from the group consisting of 10-hydroxy-2-decenoic acid, 10-hydroxydecanoic acid, decanoic acid, 2-decenoic acid, and sebacic acid, as fatty acids to enhance the collagen production by (i), to a living body, said composition being free of gluconic acid but containing (i) in an amount of at least 0.01% (w/w), in terms of the weight of L-ascorbic acid, to the total weight of said composition, and (ii) in an amount of at least 0.0001 part by weight to one part by weight of (i), in terms of the weight of L-ascorbic acid.

Determining the scope and contents of the prior art (MPEP*§ 2141.01*)

JP '656 teaches cosmetic composition having collagen synthesis accelerating effect, excellent in stability and provides cosmetic excellent in wrinkles prevention (abstract). The composition comprises L-ascorbic acid derivative, oils and fatty acids

and hyaluronic acid (paragraphs 0010, 0017, 0014, 0018). The composition further comprises thickener, perfumes, water (paragraphs 0018, 0046).

JP '921 teaches composition for treating the dermal stains or aging by using specific derivatives of L-ascorbic acid (abstract). L-ascorbic 2-glucoside is preferred derivative of ascorbic acid and is present in the composition in an amount ranging from 0.01 to 20% (solution). The composition further comprising antioxidant rutin derivative (abstract; paragraph 0017).

JP '928 teaches compounds of royal jelly origin comprising 10-hydroxy-2-decenoic acid, decanoic acid, 2-decenoic acid, sebacic acid (abstract; paragraphs 0007; claims 1 and 2). The reference teaches beautifying cosmetic comprising 1-20% of these compounds from royal jelly origin as they inhibit tyrosinase activity to control generating melanin and provide skin whitening cosmetic (abstract; paragraphs 0001, 0007, 0013). JP '921 teaches that royal jelly is widely used as health food and does not have skin irritation (paragraph 0010).

Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art (MPEP § 2141.012)

Although JP '656 teaches the combination of ascorbic acid and fatty acid, however, the reference does not explicitly teach the saccharide derivative of L- ascorbic acid as required by claim 17 and 20. JP does not teach the composition given as a food as claimed by claims 28 and 30.

However, at the time of the invention it was know by the art to accelerate the production of collagen by using combination of L-ascorbic acid derivative and fatty acid as disclosed by JP '656. The art further recognized L-ascorbic acid 2-glucoside as a preferred L-ascorbic acid derivative to treat dermal aging, and further recognized its amount as disclosed by JP '921. Fatty acids derived from royal jelly were known to be used for cosmetic purposes as beautifying agent and were further known to be used as food as disclosed by JP '928.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to accelerate collagen synthesis effect by using cosmetic composition comprises L-ascorbic acid derivative and fatty acids that provides cosmetic excellent in wrinkles prevention as taught by JP '656, and replace L-ascorbic acid derivative by 0.01-20% L-ascorbic 2-glucoside as disclosed by JP '921. One would have been motivated to do so because JP '921 teaches that composition comprising 0.01 to 20% of L-ascorbic 2-glucoside treats dermal stains or aging and further teaches that L-ascorbic 2-glucoside is preferred derivative of ascorbic acid. One would have reasonably expected accelerated collagen synthesis by using cosmetic composition comprising 0.01-20% L-ascorbic 2-glucoside and fatty acid wherein the composition successfully treats skin aging and staining. Additionally, it would have been obvious to one having ordinary skill in the art at the time of the invention to accelerated collagen synthesis by using cosmetic composition comprising L-ascorbic 2-glucoside and fatty acid as taught by the combination of JP '656 and JP '921, and further replace the fatty acid by fatty acids selected from10-hydroxy-2- decenoic acid, 10-hydroxydecanoic acid,

decanoic acid, 2-decenoic acid and sebacic acid as taught by JP '928. One would have been motivated to do so because JP '928 teaches that such fatty acids do not cause skin irritation and control generating melanin and provide skin whitening beautifying cosmetic. One would have reasonably expected accelerated collagen synthesis by using cosmetic composition comprising L-ascorbic 2-glucoside and fatty acid derived from royal jelly wherein the composition successfully treats skin aging and staining without skin irritation.

It would have been obvious at the time of the invention to provide composition comprising royal jelly as food or as cosmetic as disclosed by JP '928.

Regarding the amount of royal jelly fatty acids, one having ordinary skill in the art would have been able to determine the amount and its ratio to the ascorbic acid based on the specific desired effect.

"It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose .... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray- dried detergent by mixing together two conventional spray-dried detergents were held to be prima facie obvious.).

Resolving the level of ordinary skill in the pertinent art (MPEP *§ 2141.012)*

It would have been obvious to one of ordinary skill in the art at the time of the invention, and in view of the disclosure of the prior art to accelerate the synthesis of collagen using the claimed ingredients. The invention as a whole is taught by the combined teaching of the prior art, and considered prima facie obvious in the meaning of 35 USC § 103 (a).

Response to Arguments

16. Applicant's arguments filed 09/02/2009 have been fully considered but they are not persuasive.

Applicants argue that there is nothing in either Nanbu or Simon that teaches that one or more members selected from the group consisting of 10-hydroxy-2- decenoic acid, 10-hydroxydecanoic acid, decanoic acid, 2-decenoic acid and sebacic acid are effective in enhancing collagen production by a saccharide derivative of L-ascorbic acid. It is clear that Simon adds nothing to the combination of Nanbu and Yonekura.

In response tot his argument, it is argued that the invention as whole is taught by the combined teachings of the prior art and one cannot attack the reference individually when the obviousness is based on combination of the references. Nanbu teaches combination of hyaluronic acid and ascorbic acid to improve wrinkles. Simon teaches specific derivatives of ascorbic acid to treat skin aging. Yonekura teaches 10-hydroxy-2-decenoic acid, 10-hydroxydecanoic acid, decanoic acid, 2-decenoic acid and sebacic acid to beautify skin. "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third

composition to be used for the very same purpose .... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray- dried detergent by mixing together two conventional spray-dried detergents were held to be prima facie obvious.).

It has been held that “When a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious.” *KSR Int 'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1740 (2007) (quoting *Sakraida v. AG Pro, Inc.,* 425 U.S. 273,282 (1976)). "When the question is whether a patent claiming the combination of elements of prior art is obvious,” the relevant question is “whether the improvement is more than the predictable use of prior art elements according to their established functions.” In addition, "To determine whether there was an apparent reason to combine the known elements in the way a patent claims, it will often be necessary to look to interrelated teachings of multiple patents; to the effects of demands known to the design community or present in the marketplace; and to the background knowledge possessed by a person having ordinary skill in the art. To facilitate review, this analysis should be made explicit. But it need not seek out precise teachings directed to the challenged claim's specific subject matter, for a court can consider the inferences and creative steps a person of ordinary skill in the art would employ". Pp. 11-14. KSR INTERNATIONAL CO. v. TELEFLEXINC. ET AL. (2007).

It is well established that the claims are given the broadest interpretation during examination. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter as a whole as defined by the claims would have been *prima facie* obvious within the meaning of 35 U.S.C. 103 (a).

Conclusion

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

IG

/Isis A Ghali/
Primary Examiner, Art Unit 1611